

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

5

**Complete if Known**

Application Number	
Filing Date	
First Named Inventor	Hsing-Wen Sung
Art Unit	
Examiner Name	

Attorney Docket Number S &amp; T- 125

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-4,806,595	2-21-89	Noishiki et al.	all
		US-5,037,664	8-6-91	Kyogoku et al.	all
		US-5,085,629	2-4-92	Goldberg et al.	all
		US-5,270,446	12-14-93	Kyogoku et al	all
		US-5,322,935	6-21-94	Smith	all
		US-5,464,450	11-7-95	Buscemi et al.	all
		US-5,516,781	5-14-96	Morris et al.	all
		US-5,780,052	7-14-98	Khaw et al.	all
		US-5,929,038	7-27-99	chang	all
		US-6,103,255	8-15-00	Levene et al.	all
		US-6,162,826	12-19-00	Moon et al.	all
		US-6,200,335	3-13-01	Igaki	all
		US-6,206,931	3-27-01	Cook et al.	all
		US-6,262,083	7-17-01	Moon et al.	all
		US-6,264,992	7-24-01	Veytik-Harbin et al.	all
		US-6,395,300	5-28-02	Straub et al.	all
		US-6,423,682	7-23-02	Ballinger et al.	all
		US-6,436,703	8-20-02	Tang et al.	col. 1-6

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

2

of 5

**Complete if Known**

Application Number	
Filing Date	
First Named Inventor	Hsing - Wen Sung
Art Unit	
Examiner Name	

Attorney Docket Number S&amp;T-125

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 6,451,764	9-17-02	Lee et al.	col. 1-6
		US- 6,475,784	11-5-02	papkoff	col. 1-14
		US- 6,476,211	11-5-02	Ford et al.	col. 1-8
		US- 6,485,920	11-26-02	Ballinger et al.	col. 69-70
		US- 6,544,544	4-8-03	Hunter et al.	col. 1-86
		US- 6,545,042	4-8-03	Sung et al.	all
		US- 6,624,138	9-23-03	Sung et al.	all
		US- 6,608,040	8-19-03	Lin et al.	all
		US- 6,632,242	10-14-03	Igaki	all
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

3

of

5

Complete If Known	
Application Number	
Filing Date	
First Named Inventor	Hsing-Wen Sung
Art Unit	
Examiner Name	

Attorney Docket Number

S &amp; T-125

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	RADER DJ, "High-density lipoproteins as an emerging therapeutic target for atherosclerosis", JAMA 2003; 290(17): 2322-2324	
	2.	NISSEN SE et al., "Effect of Recombinant ApoA-I Milano on coronary atherosclerosis in patients with acute coronary syndromes", JAMA 2003; 290(17): 2292-2300	
	3.	NAGHAVI M et al., "From vulnerable plaque to vulnerable patient - part I" Circulation 2003; 108: 1664-1672	
	4	NASHAVI M et al., "From vulnerable plaque to vulnerable patient - part II" Circulation 2003; 108: 1772-1778	
	5	RODRIGUEZ AE et al., "Oral rapamycin in the treatment of diffuse proliferative in-stent restenosis in a patient with small reference vessel" J Invasiv Cardiol 2003; 15(9): 515-518	
	6	SUNG HW et al., "Feasibility study of a natural crosslinking reagent for biological tissue fixation" J Biomed Mater Res 1998; 42: 560-567	
	7	HUANG LL et al., "Biocompatibility study of a biological tissue fixed with a naturally occurring crosslinking reagent" J Biomed Mater Res 1998; 42: 568-576	
	8	SUNG HW et al., "In vitro evaluation of cytotoxicity of a naturally occurring cross-linking reagent for biological tissue fixation", J Biomater Sci Polymer Edn 1999; 10(1): 63-78	
	9	SUNG HW et al., "A naturally occurring crosslinking reagent for biological tissue fixation" in New Biomedical Materials, edited by Maris PI and Chapman D, pages 182-191 (1998) published by IOS Press	
	10	SUNG HW et al., "Crosslinking characteristics and mechanical properties of a bovine pericardium fixed with a naturally occurring crosslinking agent" J Biomed Mater Res 1999; 47: 116-126	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

4

of

5

Attorney Docket Number

S&amp;T-125

**Complete if Known**

Application Number	
Filing Date	
First Named Inventor	Hsing-Wen Sung
Art Unit	
Examiner Name	

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	11	SUNG HW et al., "Mechanical properties of a porcine aortic valve fixed with a naturally occurring crosslinking agent" <i>Biomaterials</i> 1999; 20: 1759-1772	
	12	SUNG HW et al., "In vitro surface characterization of a biological patch fixed with a naturally occurring crosslinking agent" <i>Biomaterials</i> 2000; 21: 1353-1362	
	13	TSAI CC et al., "In vitro evaluation of the genotoxicity of a naturally occurring crosslinking agent (genipin) for biologic tissue fixation" <i>J Biomed Mater Res</i> 2000; 52: 58-65	
	14	SUNG HW et al., "Fixation of biological tissues with a naturally occurring crosslinking agent: Fixation rate and effects of pH, temperature, and initial fixative concentration" <i>J Biomed Mater Res</i> 2000; 52: 77-87	
	15	SUNG HW et al., "Extraction of a naturally occurring crosslinking agent (genipin) from Gardenia fruits and its applications in biological tissue fixation" <i>Biomaterials and Drug Delivery toward New Millennium</i> , edited by Park KD et al., pages 623-632 (2000), published by Han Rin Won Publishing Co.	
	16.	TSAI CC et al., "Effects of heparin immobilization on the surface characteristics of a biological tissue fixed with a naturally occurring crosslinking agent" <i>Biomaterials</i> 2001; 22: 523-533	
	17	SUNG HW et al., "Stability of a biological tissue fixed with a naturally occurring crosslinking agent (genipin)" <i>J Biomed Mater Res</i> 2001; 55: 538-546	
	18	CHANG Y et al., "Reconstruction of the right ventricular outflow tract with a bovine jugular vein graft fixed with a naturally occurring crosslinking agent (genipin) in a canine model" <i>J Thorac Cardiovasc Surg</i> 2001; 122: 1208-1218	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.**

Substitute for form 1449B/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<i>Application Number</i>	
				<i>Filing Date</i>	
				<i>First Named Inventor</i>	Hsing - Wen Sung
				<i>Art Unit</i>	
				<i>Examiner Name</i>	
Sheet	5	of	5	<i>Attorney Docket Number</i>	S&T- 125
(Use as many sheets as necessary)					

## **NON PATENT LITERATURE DOCUMENTS**

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.**

Applicant's unique citation designation number (optional).  Applicant is to place a check mark here if English language Translation is attached.  
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*